EXHIBIT 6

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	) MDL NO. 1456
INDUSTRY AVERAGE WHOLESALE	) CIVIL ACTION
PRICE LITIGATION	) 01-CV-12257-PBS
THIS DOCUMENT RELATES TO	)
U.S. ex rel. Ven-a-Care of	) Judge Patti B. Saris
the Florida Keys, Inc.	)
v.	) Chief Magistrate
Abbott Laboratories, Inc.,	) Judge Marianne B.
No. 06-CV-11337-PBS	) Bowler

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(caption continues on following pages)

Videotaped deposition of DENNIS G. SMITH

Volume I

Washington, D.C.

Tuesday, February 26, 2008

9:00 a.m.

IN THE COURT OF THE SECOND JUDICIAL CIRCUIT
IN AND FOR LEON COUNTY, FLORIDA
THE STATE OF FLORIDA
ex rel.

VEN-A-CARE OF THE FLORIDA KEYS, INC., a Florida Corporation, by and through its principal officers and directors, ZACHARY T. BENTLEY and T. MARK JONES,
Plaintiffs,
vs.
MYLAN LABORATORIES INC.; MYLAN PHARMACEUTICALS INC.; NOVOPHARM LTD., SCHEIN PHARMACEUTICAL, INC.; TEVA PHARMACEUTICAL INDUSTRIES LTD.; TEVA PHARMACEUTICAL USA; and WATSON PHARMACEUTICALS, INC.,
DEFENDANTS.

) Civil Action
) No. 98-3032G
) Judge William L. Gary

IN THE CIRCUIT COURT OF
MONTGOMERY COUNTY, ALABAMA

STATE OF ALABAMA,
Plaintiff,
vs.
ABBOTT LABORATORIES, INC., et al.,
Defendants.

) Case No. CV-2005-219
) Judge Charles Price

Videotaped deposition of DENNIS G. SMITH, held at the law offices of Jones Day, 51 Louisiana Avenue, N.W., Washington, D.C. 20001-2113, the proceedings being recorded stenographically by Jonathan Wonnell, a Registered Professional Court Reporter and Notary Public of the District of Columbia, and transcribed under his direction.

APPEARANCES OF COUNSEL

On behalf of the United States of America:

ANA MARIA MARTINEZ, ESQ.
United States Department of Justice
99 N.E. 4th Street
Miami, Florida 33132
(305) 961-9431
ana.maria.martinez@usdoj.gov

On behalf of the U.S. Department of Health and Human Services:

BRIAN A. KELLEY, ESQ.
U.S. Department of Health & Human Services
Office of General Counsel, CMS Division
330 Independence Avenue, S.W., Room 5345
Washington, D.C. 20201
(202) 205-8702

APPEARANCES (Cont'd)

On behalf of the State of Alabama:

WINDY COCKRELL BITZER, ESQ. (via phone)
Hand Arendall LLC
1200 Park Place Tower
2001 Park Place North
Birmingham, Alabama 35203
(205) 324-4400
wbitzer@handarendall.com

On behalf of the State of California:

MATTHEW KILMAN, ESQ. (via phone)
Supervising Deputy Attorney General
Civil Prosecutions Unit
P.O. Box 85266
110 West A Street, #1100
San Diego, California 82186
(619) 688-6099

A P P E A R A N C E S (Cont'd)

On behalf of the State of Florida:

GRETCHEN WALLACE, ESQ. (via phone)
Office of the Attorney General of Florida
PL-01, The Capitol
Tallahassee, Florida 32399-1050
(850) 414-3600

On behalf of the City of New York and all New York Counties other than Nassau and Orange; the States of Wisconsin, Illinois, Kentucky, Idaho, Alaska, Hawaii, South Carolina and Mississippi:

MICHAEL WINGET-HERNANDEZ, ESQ.
Winget-Hernandez, LLC
3112 Windsor Road, Suite 228
Austin, Texas 78703
(512) 858-4181
michael@winget-hernandez.com

A P P E A R A N C E S (Cont'd)

On behalf of Ven-A-Care of the Florida Keys, Inc.:

JOSEPH C. WILSON, ESQ.
Cotchett, Pitre & McCarthy
San Francisco Airport Office Center
840 Malcolm Road
Burlingame, California 94010
(650) 697-0577
jwilson@cpmlegal.com

On behalf of Abbott Laboratories, Inc.:

R. CHRISTOPHER COOK, ESQ.
SEAN P. MALONE, ESQ.
Jones Day
51 Louisiana Avenue, N.W.
Washington, D.C. 20001-2113
(202) 879-3939
christophercook@jonesday.com
spmalone@jonesday.com

A P P E A R A N C E S (Cont'd)

On behalf of Bristol-Myers Squibb:

SANDHYA P. KAWATRA, ESQ. (via phone)
Hogan & Hartson
875 Third Avenue
New York, New York 10022
(212) 918-3000
spkawatra@hhlaw.com

On behalf of Dey, Inc., Dey, L.P. and Mylan:

NEIL MERKL, ESQ.
Kelley, Drye & Warren LLP
101 Park Avenue
New York, New York 10178
(212) 808-7811
nmerkl@kelleydrye.com

A P P E A R A N C E S (Cont'd)

On behalf of Endo Pharmaceuticals:

VICTOR RORTVEDT, ESQ.
Arnold & Porter
555 Twelfth Street, N.W.
Washington, D.C. 20004
(202) 942-5000

On behalf of Roxane Laboratories and Boehringer Ingelheim:

JOHN W. REALE, ESQ.
Kirkland & Ellis
200 East Randolph Drive
Chicago, Illinois 60601
(312) 861-3452
jreale@kirkland.com

A P P E A R A N C E S (Cont'd)

On behalf of Sandoz, Inc.:

LARA A. BERWANGER, ESQ. (via phone)
White & Case LLP
1155 Avenue of the Americas
New York, New York 10036-2787
(212) 819-2549
lberwanger@whitecase.com

On behalf of Schering-Plough Corporation, Schering Corporation and Warrick Pharmaceuticals Corporation:

GINGER APPLEBERRY, ESQ. (via phone)
Locke, Liddell & Sapp
2200 Ross Avenue, Suite 2200
Dallas, Texas 75201
(214) 740-8459
gappleberry@lockeliddell.com

A P P E A R A N C E S (Cont'd)

ALSO PRESENT:

CONWAY BARKER, videographer

C O N T E N T S

E X H I B I T S

(Exhibit Abbott-Smith 486 was retained by Mr. Cook)

P R O C E E D I N G S

(9:25 a.m.)

THE VIDEOGRAPHER: In the United States District Court for the District of Massachusetts In Re: Pharmaceutical Industry Average Wholesale Price Litigation, related to the United States of America ex rel. Ven-A-Care of the Florida Keys Incorporated versus Abbott Laboratories Incorporated et al., Case Number 01-CV-12257 (PBS) and other cross noticed cases, this is the deposition of Dennis G. Smith.

Today's date is February 26th 2008. The location is Jones Day, 51 Louisiana Avenue, Northwest, Washington, D.C. Will counsel please identify yourselves and state whom you represent?

MR. COOK: Christopher Cook from Jones Day. We represent Abbott Laboratories, Inc.

MR. MERKL: Neil Merkl from Kelley Drye. We represent the Dey companies.

MR. REALE: John Reale from Kirkland & Ellis and I represent the Boehringer entities.

MS. MARTINEZ: Ani Martinez. I

represent the United States.
MR. KELLEY: Brian Kelley. I represent the Department of Health and Human Services.
MR. WILSON: Joe Wilson with Cotchett, Pitre & McCarthy on behalf of Ven-A-Care, the relator in this matter.
MR. WINGET-HERNANDEZ: Michael Winget-Hernandez. I'm here on behalf of the New York Counties and the City of New York in MDL 1456 other than Orange and Nassau; also on behalf of the states of Wisconsin, Illinois, Kentucky, Alaska, Hawaii and Idaho to the extent that they have been cross noticed here.
THE VIDEOGRAPHER: Those on the phone, could you identify yourselves please?
MS. BITZER: This is Windy Bitzer. I represent the state of Alabama.
MR. KILMAN: Matt Kilman on behalf of the state of California.
MS. WALLACE: Gretchen Wallace on behalf of the State of Florida attorney general's office.

MR. RORTVEDT: Victor Rortvedt on behalf of Endo Pharmaceuticals, Inc.
MS. APPLEBERRY: Ginger Appleberry, Schering, Schering-Plough and Warrick Pharmaceuticals.
MS. BERWANGER: Lara Berwanger from White & Case on behalf of Sandoz, Inc.
MS. KAWATRA: Sandhya Kawatra, Hogan & Hartson on behalf of Bristol-Myers Squibb Company.
THE VIDEOGRAPHER: The court reporter is Jon Wonnell. The video camera operator is Conway Barker, both on behalf of the Henderson Legal Services. This deposition commences at 9:27.

Whereupon,
DENNIS G. SMITH,
called as a Witness, was duly sworn by Jonathan Wonnell, a Notary Public in and for the District of Columbia, and was examined and testified as follows.

EXAMINATION BY COUNSEL FOR ABBOTT LABORATORIES
BY MR. COOK:
Q. Good morning, Mr. Smith. My name is Chris Cook. I'm with Jones Day and I'll be taking your deposition today. To start with, could you please tell the court reporter your name and spell it?
A. Dennis D-e-n-n-i-s, G., Smith, S-m-i-t-h.
Q. Where do you live, Mr. Smith?
A. In Springfield, Virginia.
Q. And what's your business address?
A. 200 Independence Avenue, Southwest, Washington, D.C.
Q. Do you have any immediate plans to change either your residence or your business position?
A. The election will change my business address.
Q. Will we be able to reach you through Ms. Martinez if we need to depose you in the

future?
A. Sure.
Q. If you do change jobs and leave the administration after the election, what would be the best way to get in touch with you after that?
A. At this point I have no idea.
MS. MARTINEZ: Obviously through counsel would be one way.
MR. COOK: Sure. And so you'll continue to represent Mr. Smith even after he leaves government employment?
MS. MARTINEZ: Well, obviously that's something we would discuss with him. If he requests that of course we would do that.
BY MR. COOK:
Q. What's your current position?
A. I'm the director of the Center for Medicaid and State Operations.
Q. With what organization?
A. The Centers for Medicare and Medicaid Services.
Q. Would you understand it if I refer to

what would become the regulations to implement the MMA.
Q. Prior to implementation of MMA 2003, how was it that Medicare paid for those few drugs for which Medicare Part B did pay for separately?
A. I don't know. I couldn't explain.
Q. And so you probably also couldn't explain -- or you can tell me whether you can't -- how it was that MMA 2003 changed the manner in which Medicare paid for drugs under Part B?
A. I couldn't explain. Certainly lots of other people can within the agency.
(Exhibit Abbott-Smith 486 was marked for identification.)
BY MR. COOK:
Q. Mr. Smith, let me hand you what I've marked as Abbott Exhibit 486. For the record, Exhibit Abbott 486 bears Bates numbers HHD 101-0489 through 0492. It is a letter on CMS letterhead to state Medicaid director. And it appears to be from you, although it is an unsigned copy, with a summary statement added to

the back of the -- what appears to be a draft letter.
Do you recognize Exhibit 486?
A. I'd have to read it. I don't recognize it offhand.
Q. If you could take the time -- I'm sorry.
A. Generally things that are sent out over my signature would have my signature. This does not. So I don't know if this is --
Q. I'm sorry. You were saying?
A. So I don't know offhand if it's an earlier draft or -- usually if there was a final it would have my signature or indicate that it had been signed.
MS. MARTINEZ: Counsel, just on a very quick glance at this document it looks to me like possibly it's a document that we should have asserted privilege over. I'd just like to have an opportunity to discuss that with in-house counsel. Is it possible for you to move on to another exhibit or give us a break?

MR. COOK: Oh, I'm happy to go off the record. I would say that we were unable to locate a final version of this. And so this is the only version we have. So I don't have another version of this to use. But let's go off the record and let you discuss it.
THE VIDEOGRAPHER: Off the record at 1:02.
(Recess.)
THE VIDEOGRAPHER: On the record at 1:18.
MS. MARTINEZ: This is Ani Martinez on behalf of the United States. We reviewed the document that's been marked as Abbott Exhibit 486, which has the Bates labels HHD 101-0489 through HHD 101-0492. It appears to us that this is a document that was inadvertently disclosed and we're asserting the deliberative process privilege with respect to it.
MR. COOK: We disagree, but I'll move on to another document. If you'll give me a minute I'll pull it out to mark it.

MR. MERKL: For the record, we also disagree.
MS. MARTINEZ: And in case I didn't use the words recall, we're recalling the document at this time.
(Exhibit Abbott-Smith 487 was marked for identification.)
BY MR. COOK:
Q. Mr. Smith, I'll hand you a document that I've marked Exhibit 487. And at the same time as you're looking at that I'll get your counsel to pull out a copy of Exhibit 328.
MR. COOK: And I apologize. I don't know what volume it's in, Ani.
MS. MARTINEZ: That's okay.
BY MR. COOK:
Q. While you're looking at Exhibit 487, let me --
MR. WINGET-HERNANDEZ: 328?
MR. COOK: Yes. 328.
BY MR. COOK:
Q. -- let me indicate for the record

Exhibit 487 is a document that was produced to us yesterday. It does not have Bates numbers. However, it is a copy of a memo from CMS dated October 20, 2002. It is from the director of the Center for Medicaid and State Operations it appears to have gone out over your signature. It is addressed to Tom Scully, the administrator, and Rubin J. King-Shaw Jr., the deputy administrator and chief operating officer of CMS.

It is redacted for much of pages 1, 2 and a part of page 3. And on the fifth page it bears your signature and it bears the signature of Tom Scully with a date of what looks like November 2, 2002 under the decision indicating approved.

Mr. Smith, do you recognize Exhibit 487?

A. If you'll give me a minute to read through it just to refresh my memory.

Q. Please do.

A. This would have been 2002.

Q. So it appears.

A. (Reading.) Okay.

Q. Do you recognize the document?

A. I recall it, yes.

Q. Is that your signature at the end of the document?

A. Yes, it is.

Q. Do you recognize that as Mr. Scully's signature under approved?

A. Yes.

Q. What is this memorandum?

A. This is -- this would have been an internal memo, that we would have prepared for guidance on review of state plan amendments. When states do want to change their payment methodologies or any type of provider, then they would submit plan amendments. This was still relatively early in the administration. We were trying to get some guidance on how to handle the review.

I think that in general these are helpful. But as it indicates on the final recommendation that we would look at the

individual circumstances in the state as well as its supporting documentation and rationale. So I think this is guidance for us as we would review state plan amendments as they came in.

Q. Who drafted this memorandum?

A. I can't say with absolute certainty, but it would most likely come from my staff.

Q. Do you know who within your staff is most likely to have had the pen on this document?

A. Most likely it would be Larry Reed or -- Larry at the time certainly was working on the pharmacy issues. I don't recall if Deirdra Duzor had moved over to the pharmacy at that point in time yet or not. But Larry is certainly our expert; was at that time, and continues to be so today.

Q. Did you participate in determining whether to redact this document?

A. I don't believe I did.

Q. Do you know what it is that has been redacted from this document?

A. I don't recall.

Q. How was it that the issue of factors for approving or denying state plan amendments relating to the payment for prescription drugs became an issue in around October of 2002?

A. As I indicated, this is still relatively early in the administration. We were getting state plan amendments in. This was -- as I said, I think we were just trying to make certain we were getting some general guidance on how to handle it.

Q. Was there any event that occurred that you recall that caused this to become an issue at about this time?

A. I don't recall any specific event.

Q. What are the standards that govern the approval or disapproval of state plan amendments?

A. Well, the law, the regulations --

Q. Yes, sir. The law and regulations. Could you describe to me what it is that the legal parameters are that govern CMS's approval or disapproval of state plan amendments?

A. In general, as we discussed earlier,

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Medicaid overall is supposed to be paying in an efficient and economical manner. The regulations refer to -- I'm trying to recall the exact wording -- I think best estimates of estimated acquisition cost, a reasonable dispensing fee. So I think as we had discussed earlier, that it is, again, sort of those competing interests that we often find ourselves in to Medicaid being a program to provide access for poor people and also balancing that with being a prudent purchaser.

So I think the -- as the paper indicates, as you go through the options, breaking it down as reimbursement typically is, one, on the ingredients side and, secondly, on the dispensing side, because you're paying at the counter for outpatient drugs, typically paying the pharmacist.

As I said, this -- again, I think we were just looking for some general guidance as to review them as they come in. But it clearly also indicates that we would be looking at any of the

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supporting documentation that the states provided us to justify their plan amendments.

Q. So it's your understanding that the pertinent regulations require CMS to approve state plan amendments that in the aggregate will pay the estimated acquisition cost plus a reasonable dispensing fee for prescription drugs; do I have that correct?

A. Well, in the aggregate refers to specifically drugs on the FULs. Obviously we pay for drugs that aren't on FULs also.

Q. Yeah. Let me go ahead and pull the regulation. That may be easier.

MR. COOK: Ani, could you pull Exhibit 284? I don't know which volume it's in. I'm sorry again.

MS. MARTINEZ: Don't worry. I'm getting good at this.

BY MR. COOK:

Q. Okay. For the record, Exhibit 284 is a copy of page 28648 and volume 52 number 147 of the Federal Register dated July 31, 1987. If I

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could get you to turn to the second to the last page of that document, I believe it contains the regulation that from 1987 until the last couple of years governed the upper limits for payments for prescription drugs by state Medicaid programs. I'll turn your attention to section 447.331. It's in the third column from the left, halfway down.

A. Mm-hmm.

Q. And I believe the provision that you want to look at is subparagraph B, as in boy, entitled "other drugs." And if you could follow with me. Do you agree with me that this applies to brand name drugs and to multiple source drugs for which no FUL has been established, correct?

A. If you'd give me a minute to read it, please.

Q. Oh, certainly.

A. (Reading.) Okay.

Q. Just to walk through the regulation, do I understand correctly that paragraph A of section 447.331 relates to the aggregate upper

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limits for payment of drugs for which a federal upper limit has been established?

A. 331 does refer to that. But I think it's also important the definition provided above in 301 also applies. Which is "The estimated acquisition cost means the agency's best estimate of the price."

Q. Correct.

A. So I think that modification is an important one.

Q. Certainly. But before getting to the term estimated acquisition cost in the regulation, as I understand the way the regulation breaks down -- and you can tell me if I have it wrong -- in section 447.331 paragraph A governs the upper limit for payments in the aggregate for drugs for which a federal upper limit has been established, right?

A. Again, better people in the agency to walk you precisely through the drug. But A also starts out "except for brand name drugs." So again, you have to read the regulation in its

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entirety.
Q. Precisely. And so except for brand name drugs paragraph A relates to multiple source drugs for which a federal upper limit has been established, right?
A. Yes.
Q. And then subparagraph B relates to --
MS. MARTINEZ: No, wait. I know what you're trying to do, Chris. And I'm sorry to interrupt.
MR. COOK: Sure.
MS. MARTINEZ: But it seems that subsection A says "except for brand name drugs that are certified in accordance with paragraph C," blah, blah, blah, and then in B it says "the agency payments for brand name drugs certified in accordance with paragraph C." I'm just saying probably the best thing to do is if you want to read the full text then you've got it accurately.
MR. COOK: Actually, I'm just looking for Mr. Smith's understanding of his obligations or the agency's obligations for approving state

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plan amendments. And it may be easier to summarize it completely.
BY MR. COOK:
Q. Is it your understanding that in approving state plan amendments for the payment of drugs not subject to a federal upper limit that it was the obligation of the agency to approve the state plan amendment only to the extent that in the aggregate payment levels would not exceed the lower of estimated acquisition cost or the provider's usual and customary charges to the general public?
MS. MARTINEZ: I'm sorry. I understand what you're saying, Chris. But you missed estimated acquisition cost plus reasonable dispensing fee established by the agency or provider's usual and customary charges to the general public.
MR. COOK: Sure. Let me ask the question again. I appreciate it.
BY MR. COOK:
Q. Mr. Smith, is it your understanding

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that CMS when reviewing state plan amendments was required to approve the state plan amendment only to the extent that the agency has determined that the payment levels in the aggregate would not exceed either on the one hand estimated acquisition cost plus a reasonable dispensing fee or on the other hand the provider's usual and customary charges to the general public?
A. I think you are linking too many things there together.
Q. Okay. Explain to me what --
A. Let me step back in terms of approval versus disapproval. Again, Medicaid is generally delegated to the states and they have the authority to set provider reimbursement for all types of providers. The issue to us is disapproving a state plan amendment. So the guidance that you saw in the previous exhibit for the memorandum, when you put those on top of regulations -- and again, in their entirety, because they certainly say other things -- we are not so much taking an affirmative position.

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The burden is on us to take a disapproval on a state plan amendment, and we can disapprove state plan amendments if they are not consistent with the entirety of the Medicaid regulations, which include efficiency and economy, et cetera.
Q. Realizing that we'll come back in a moment to the other considerations that derive from the other aspects of the Medicaid program, can you explain for me what you understood to be the regulatory requirements that you had to apply in deciding whether or not to disapprove a state plan amendment under the regulations marked as Abbott Exhibit 284?
A. Well, as I stated, when a state changes its payment methodology, and whether, again, a state even -- this regulation goes back to 1987, which was well before my time. And I certainly can't tell you what they meant in 1987. But with the entirety of the regulations on -- again, using all of the definitions in the regulation, including the agency's best estimate, again, we

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would ask a state -- if sort of outside those parameters you saw a big disparity amongst the states you would say, well, how did you get that, where did you get that from.

So in general if they met the requirements of the regulation then it would go into effect.

Q. But you're getting ahead of me a little bit. My question to you is what you understand -- and since 2001 have understood -- the regulatory requirements to be. And we'll get to the policy decisions that affect how that's implemented in a moment.

MR. WINGET-HERNANDEZ: Objection, form.

Q. And I'll ask that as a more clear question. Could you describe to me what you understood those regulatory requirements to be?

MR. WINGET-HERNANDEZ: Objection, form.

A. The regulatory requirements are for a state to pay its reimbursement for prescription drugs to meet the entirety of the regulations that include that they are based on the agency's

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best estimate of the acquisition cost and a reasonable dispensing fee.

Q. And so I understand --

A. And if we believe them not to meet those then it would be -- well, a state, if it didn't meet those requirements or fit within those parameters, we would have -- we would question the state further. And again, as the October 2002 memo states, we would look at the individual circumstances in the state as well as its supporting documents.

So the documentation of how do you meet the regulations, they fit together. You can't just pull one piece out and say that represents the entirety. That would be not accurate.

Q. And so if one were -- let me back up just a little bit. I apologize. Tell me if I'm correct in hearing what you're telling me. Is it that looking simply at the definition of estimated acquisition cost without taking into account all of the goals of the Medicaid program would provide an incomplete picture in what you

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were doing in reviewing state plan amendments?

MR. WINGET-HERNANDEZ: Objection, form.

MS. MARTINEZ: Objection, form.

A. Every piece of a regulation is there for a purpose and they all fit together.

Q. But the standards that you felt governed the approval of state plans extended beyond merely the definition in section 447.301 and the language in 447.331 and extended to the other goals and purposes of the Medicaid program, correct?

MR. WINGET-HERNANDEZ: Objection, form.

A. I'm not following you.

Q. Sure. You would agree with me that one could read the language in section 447.301 and 447.331 to allow for the approval of a state plan amendment only if it with precision, as much as possible, estimated the invoice price of the drugs to the pharmacy? That would be one interpretation of this language, correct?

MR. WINGET-HERNANDEZ: Objection to form.

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MR. KELLEY: Objection to form.

A. The regulation itself doesn't say invoice price, I don't think. So, I mean, you're asking me to read things into the regulation where the words aren't there.

Q. Did you understand this regulation to require you to approve a state plan only if the formula proposed by the state would pay as the ingredient cost an amount that approximated the invoice price for drugs to pharmacies?

MS. MARTINEZ: Objection, form.

A. I'm going back to my previous answer. You are -- you have to look at it in the entirety. You can't just pick one piece of it out and say would you approve or disapprove on that alone. You have to look at the entirety.

Q. I actually intended that to be a softball question.

A. Okay.

Q. Is it fair to say that you did not see this regulation as requiring you -- or requiring states, rather -- to establish a formula that set

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as the payment level the estimated invoice price for the drugs to pharmacies?
MR. WINGET-HERNANDEZ: Objection, form.
Q. That that was not the standard that was being applied here?
MR. WINGET-HERNANDEZ: Objection, form.
Q. Let me ask it in another way that I think might hew closer to what you're telling me. You would agree with me that it would be an overly simplistic view of this regulatory scheme to look simply at the acquisition cost of pharmacies for drugs and have that be the only determining factor about whether or not a state plan properly estimated the estimated acquisition cost for drugs?
MR. WINGET-HERNANDEZ: Objection to form.
MR. KELLEY: Objection to form.
A. I think the construction does include both acquisition cost and a dispensing fee.
Q. Looking solely at the estimated acquisition cost component of that formula, what

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is your understanding of what the acquisition cost was that -- let me skip that.
Can you give me some examples of how states appropriately estimated the acquisition cost for the pharmacy payment portion of their prescription drug payments?
A. I think our website can give you for every state their reimbursement formula of -- they're on our web. So I don't know if it's one of the exhibits. But those are all obviously state plan amendments that have been approved to reflect reimbursement.
Q. But can you give me an example?
MR. WINGET-HERNANDEZ: Objection to form.
A. There are a number of different variations. Again, states using AWP minus a percentage that's further modified by maximum allowable cost. That's further modified by a wholesale acquisition cost. So states have flexibility, all of which would be approvable, because again, Medicaid is designed to provide

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the states with flexibility.
This is not a national you will pay all providers one way. There is flexibility for the states to choose among different ways. And states clearly do pay differently. But they are approvable. Again, dating back to 1987, that people who reviewed state plan amendments at that time, Medicaid was paying for prescription drugs, and clearly they approved state plan amendments that were based on a variety of different formulas.
But I believe in all cases it is a combination of acquisition cost and dispensing fee. I could be corrected on that, but that's my understanding. I can't think of one that pays only one way.
Q. And so a state plan amendment would come to your office and propose to pay for prescription drugs at AWP minus 14 percent plus a dispensing fee of some amount of money. Do you follow me?
A. That would be an example.

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Q. And your staff would look at that proposal and look at whatever justifications are for paying AWP minus 14 percent and decide whether or not under the regulatory framework staff is required to disapprove that state plan amendment or allow it to go forward. Do I have it correct so far?
A. I think that's a fair characterization.
Q. In looking at that formula of AWP minus 14 percent what is your understanding of the questions that the CMS staff would ask themselves in order to determine whether or not that formula meets the goals of the Medicaid programs and the statutory and regulatory requirements?
A. I can give you a recent example of where state plans have recently come in to us to increase the dispensing fee and our response back to the state was, again, documentation, how do you document the requested increase. In I believe one specific case we disapproved the state plan amendment because the request for the increase in dispensing fee was in excess of what

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the study supported.
Q. Now, the answer you gave me related to some of the questions that were asked recently for a state plan amendment that related to an increase in a dispensing fee, correct?
A. That was a particular to increase the dispensing fee.
Q. There are a number of occasions on which state plan amendments were submitted to you to either increase or decrease the ingredient cost portion expressed by a percentage off of AWP, correct?
A. I can't think of a specific one, but that would -- it seems likely that state plan amendments making changes would have come in to us.
Q. And my question to you is when those state plan amendments came across the desk of your staff seeking to change the ingredient cost portion of the payment, what are the questions that you expect your staff to be asking to determine whether that formula meets the

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regulatory requirements and the other goals of the Medicaid program?
A. Well, I think it's also fair to recall that we have staff who have years of experience in reviewing these state plans and the entire history, et cetera. I think that the specific example that I just gave you on the dispensing fee we asked them to back that up with supporting documentation. I think in -- I mean, in large part I would just rely on the expertise of my staff in putting together whatever appropriate questions they would have to ask the state.
Q. You would agree with me that it is not so simple as to simply look at the formula and compare it to what the average price in the marketplace is for individual drugs to determine whether that formula meets the regulatory requirements, correct?
MR. WINGET-HERNANDEZ: Objection to form.
MS. MARTINEZ: Objection to form.
MR. KELLEY: Objection to form.

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A. I'm not certain what you're meaning in terms of individual drugs. Because you're adopting a formula that pays on all the drugs. You don't generally pick -- you don't generally isolate this drug from that drug. Now, you may pick a formula that distinguishes a brand name from a generic. But an individual drug price, you generally are picking formulas that you pay on all of the drugs.
Q. You're actually getting ahead of me a little bit.
A. Okay.
Q. You would agree with me then that it certainly would not be appropriate to look at the estimated acquisition cost regulations and compare it to the average price of a single drug in determining whether that regulation was being complied with by the state, right?
A. I'm not certain what you mean.
Q. It would be an incomplete picture to pick one drug out of the formulary, look at that drug's price in the marketplace and determine

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that the estimated acquisition cost regulations had somehow not been complied with, correct?
MR. WINGET-HERNANDEZ: Objection, form.
A. We are approving or leading to disapproval of a state plan that deals with all drugs that a state is paying for on that formula. If you are looking at individual drugs I don't think that discussion would typically come up in a state plan amendment. It may come up someplace else, such as a review of providers. It could come up on a -- in a different form. But it generally wouldn't come up on a state plan amendment review.
Q. And state plan amendment reviews are the only context in which this regulation relating to estimated acquisition cost comes into play, right?
MS. MARTINEZ: Objection, form.
A. I wouldn't say it's the only place that it would come into play.
Q. Can you tell me any other place in which it comes into play in your administration

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of the Medicaid program?
A. I think it gives us the ability to use at any time to question whether or not a state is administering its program appropriately. Once a state plan amendment is approved we still have the authority to go back and say are you following your state plan, are you paying according to your state plan, do you -- there are audits.
The Congress just recently, for example, gave us specific authority and funding to do audits of providers. Generally CMS did not have those resources prior to 2005. We now have those resources to go and look at a particular drug or a particular -- to get to the specific particular that you're talking about, we have that authority as well.
So that's what I meant by I don't think we -- again, you could apply things in different settings other than solely just a state plan amendment approval.
Q. All right. But you would agree with me

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that the requirement that payments not exceed estimated acquisition cost plus a reasonable dispensing fee applies only in the aggregate?
A. Well, again, I would make sure you modify it. It's the best estimate and reasonable dispensing fees.
Q. And that applies only in the aggregate, correct?
MR. WINGET-HERNANDEZ: Objection, form.
A. If you'd give me a minute to read it again. I'm not certain whether the precise wording refers only to the acquisition or to the dispensing fee as well.
Q. All right. And I can actually read the language to you here.
A. Again, you have folks who have much more intimate knowledge who have a lengthy history of applying these regulations beyond what I do.
Q. All right. Well, I'll just read the language here and you can follow along with me. I'm beginning at the subparagraph B under other

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drugs --
A. Mm-hmm.
Q. -- with the line that begins "must not exceed." And it's referring from the first line to the payments. And I'm cutting out the descriptors in between. But it says that the payments "must not exceed in the aggregate payment levels that the agency has determined by applying the lower of the, one, estimated acquisition cost plus reasonable dispensing fees established by the agency, or, two, provider's usual and customary charges to the general public."
A. Mm-hmm.
Q. Would you agree with me that the requirement that estimated acquisition cost be paid, or no more than estimated acquisition cost plus a reasonable dispensing fee be paid, applies only in the aggregate?
MR. WINGET-HERNANDEZ: Objection to form.
A. Again, you read the regulation in its

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entirety the purpose is to deal with an aggregate amount, not an individually priced drug. The federal government does not -- in the Medicaid program, anyway, we do not price set for individual drugs. Presumably that's a policy choice that could have been made years ago. But that isn't how Medicaid was constructed.
Q. What does it mean for the payment limitation to be in the aggregate rather than on a drug by drug basis?
A. I think precisely that, all of them put together.
Q. And so a state could decide to pay more for one drug, less for another drug, but as long as once you add them all up in the end in the aggregate it is at the appropriate level, that would meet federal regulatory requirements, right?
A. That is correct. States could pay even more if they wanted to. But this is a restriction of how much we would be willing to match.

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Q. Given what you know about how state Medicaid programs work as the former director of Virginia Medicaid, you would expect that there would be some drugs that pay more, some drugs that pay less in that way rather than each and every drug being paid at exactly estimated acquisition cost, correct?
MS. MARTINEZ: Objection, form.
MR. KELLEY: Objection, form.
A. I really don't remember how we did it in Virginia. Usually -- and what edits you put into the system. Whether we did it on the individual or not, I don't remember how Virginia did it.
Q. Well, it's your understanding that the vast majority of states are paying based upon some sort of formula, whether it's AWP minus a percentage or WAC plus a percentage, correct?
A. That's correct. And MACs also.
Q. And you would expect that from drug to drug and even from provider to provider the difference between acquisition cost and the AWP

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would vary, correct?
A. Well, a couple of distinctions to make. In terms of provider to provider generally you would not say I'm going to pay Pharmacist Smith more than Pharmacist Jones.
Q. Precisely.
A. You may want to say I'm going to have a class of providers to where rurals are paid differently than urbans. You might say I'm going to pay independents differently than I do chains.
Q. So two providers, each buying ten different drugs would get the same formulaically derived reimbursement payment, correct? AWP minus 10 percent, right?
MR. WINGET-HERNANDEZ: Objection, form.
A. Again, states have a good deal of flexibility on how they determined their reimbursement levels. And in a combination with their acquisition cost and dispensing fees.
Q. But based upon your experience you would expect that the application of a single formula across many different types of providers

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and many different types of drugs and many individual drugs and many individual providers would result in varying differences between the payment amount and the acquisition cost for each provider, each drug, correct?
MS. MARTINEZ: Objection, form.
A. I think the reasonable expectation, though, is that there wouldn't -- I think any Medicaid agency would be very concerned with too much variation. And again, it's hard to -- I can't properly define what too much variation is. But I think it is -- these are not static things. And agencies typically would want to continue to review -- this isn't onetime only, here's my state plan and just let the money flow. I think states typically would continue to look at to see if there is variation among providers, among types of drugs as well.
So although I would agree there is some variation, I think you are looking for things that says, well, there's something else going on here rather than just the market.

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Q. But you would agree with me that the application of this formula to a variable market results in variations between the payment amount and the acquisition cost?
A. And average is an average. I mean, that assumes that there are higher and lower and you're taking an average. But as I said, I think you also would be looking for variations to suggest that we're not dealing with just an average any longer.
Q. Do you have out in front of you Exhibit 328?
MS. MARTINEZ: It's in that book. This particular book doesn't have it. It says recalled on the basis of privilege.
MR. COOK: Ah. This was the one that you originally recalled and then --
MS. MARTINEZ: We asserted privilege. However, we did not do the recall because it had been produced in 2004. So it was impractical to pull it from everybody in the MDL, but we asserted that the document was privileged. But I

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think you may have it somewhere else.
MR. COOK: Let's go off the record for a moment and I'll have somebody bring down some extra copies of that document. I didn't realize that they were taken out of the booklets and not put back in.
MS. MARTINEZ: Okay.
MR. COOK: Off the record.
THE VIDEOGRAPHER: This is the end of tape 3. Off the record at 2:06.
(Recess.)
THE VIDEOGRAPHER: This is the beginning of tape 4 in the deposition of Mr. Smith. On the record at 2:21.
BY MR. COOK:
Q. Before going back to the documents -- and I brought a copy of Exhibit 328 that should be there in front of you, Mr. Smith.
MR. COOK: Ms. Martinez, could you tell us -- we didn't receive, given the time restrictions, a privilege log describing what the basis for the redactions are in Exhibit 487.

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Could you for the record so we know what the basis is for the redactions?
MS. MARTINEZ: Yes. It's a deliberative process privilege.
MR. COOK: And also for the record I'm about to get to it with Abbott Exhibit 328. But it's my understanding that Abbott Exhibit 328 is a draft of Exhibit 487, which is the final, and that -- that was actually the reason Exhibit 487 was produced because we had requested the final version of Exhibit 328, which is the draft. And just for the record, it's our position that the production of the draft and the failure to litigate return of the draft would constitute a waiver of any privileges that would apply. So we would ask that an unredacted version be produced.
MS. MARTINEZ: Yeah. Obviously we disagree on the issue of waiver for multiple reasons.
MR. COOK: Right. And of course preserving our argument that it's not privileged in the first place.

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MS. MARTINEZ: Right.
MR. MERKL: We also join Mr. Cook's reservation. And I would also point out that the extensive testimony on the record also waives the privilege as well.
MR. REALE: Roxane joins as well.
MS. MARTINEZ: Again, we disagree on the issue of waiver for multiple reasons.
BY MR. COOK:
Q. Mr. Smith, could you open up Abbott Exhibit 328 and tell me whether you've seen that document before?
A. I'd have to take a moment to read through it.
Q. Please do. Take your time.
A. Okay. (Reading.)
Q. Have you read the document, Mr. Smith?
A. Yes.
Q. Have you seen this document before?
A. I don't recall it offhand.
Q. Do you recognize this document, Exhibit 328, as a prior draft of the language that is

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redacted from Exhibit 487?
A. As I said, I don't recall that that -- that it fits into that document.
Q. You would agree that Exhibit 487 is over your signature, correct?
A. Yes.
Q. And if in fact Exhibit 328 is a prior draft of language that appears under the redacted portions of Exhibit 487, you have no problem adopting the statements contained in Exhibit 487 because they went out over your signature, correct?
MS. MARTINEZ: Objection, form.
A. What you just related was this was a draft. I may not have seen this draft. So I don't know.
Q. I'm not able to ask you about statements that went out over your signature in Exhibit 487, although -- because it's redacted, right?
A. The document is redacted, yes.
Q. Would you agree with me that whatever

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is underneath this redaction tape that went out over your signature would be thoughts and concepts and statements that are attributable to you, Mr. Smith?
MS. MARTINEZ: Objection, form.
A. The final document would have had my review of any of the other information. But as I said, I don't recall 328 offhand, so I don't know what draft it was or --
Q. Having read Abbott Exhibit 328, are there any statements in it that you disagree with?
A. I didn't read it that carefully to go through whether I would have any --
Q. Okay. Let's go off the record and you can read it as carefully as you would like and we can go back on the record and you can tell me if there are any statements in Exhibit 328 that you disagree with.
A. Okay.
MR. COOK: We can go off the record.
THE VIDEOGRAPHER: Off the record at

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2:29.
(Recess.)
THE VIDEOGRAPHER: On the record at 2:34.
BY MR. COOK:
Q. Having reviewed the document in more detail, Mr. Smith, can you now remember whether this is a preliminary draft of the redacted portions of Exhibit 487?
A. I still don't particularly remember the two documents being together.
Q. And so my next question I think may be self answered. And that is, do you know which of the statements in Exhibit 328 may have ultimately made their way into the redacted portions of Exhibit 487?
A. I don't know.
Q. Are there any statements in Exhibit 328 with which you disagree?
A. I think I would take exception to the very first statement in that it I think gives a -- reading it in the context that we have here in

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the questioning that we've had, suggesting that there is no authority for us to act, where I think there are other places in the Medicaid statute that still gives us the authority to -- I think that's an overly broad statement that I think would be --
Q. And that's the sentence that reads "Although there are no statutory provisions for payment rates for Medicaid drugs, states are required to set rates in accordance with regulations at 42 C.F.R. 447.301 to 333"?
A. There are still general provisions in Title XIX that still apply as well.
Q. So how would you modify that sentence to make it accurate?
MR. WINGET-HERNANDEZ: Objection, form.
MR. COOK: What's the form objection?
MR. WINGET-HERNANDEZ: The form objection is that the question assumes that the witness is under some obligation to rewrite this statement. I don't think he is under that obligation. He's already described to you what

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his disagreement with it is.
BY MR. COOK:
Q. How would you change this statement to make it accurate, if at all?
A. The statement strikes me as overly broad and does not account for other authorities in the statute that are pertinent to state plan amendments, pertinent to the integrity of the Medicaid program. I think it is an overly broad statement that would not accurately reflect a specific instance that the agency or a state agency might believe would be in the best interest of the Medicaid program.
So I think it leaves too much -- I think it is too broad of a statement that doesn't reflect the entirety of federal authority or state authority in the management of the Medicaid program.
Q. Well, breaking this sentence down a little bit, the first half, do you disagree with the first half of the sentence, that "There are no statutory provisions for payment rates for

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Medicaid drugs"?
A. I think that is an overly broad statement, because you I believe still could appropriately -- the other provisions about efficiency and economy in 19.02 I believe apply to the entire Medicaid program, which would include drugs.
Q. And so could you explain to me how those statutory provisions affect the payment rates for Medicaid drugs?
A. Because Medicaid -- it's an obligation to pay and in terms of efficiency and economy. That is broad statutory authority for the federal government in its oversight role, which this statement in itself would ignore.
Q. So to the extent that that statement made its way into the final memo that went out over your signature, if we were able to peek under the skirt, it would be inaccurate, right?
MR. KELLEY: Objection to form.
A. I think it is, as I said, an overly broad statement that I think would -- it's

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further modified with a greater understanding of what the entirety of Title XIX provides.
Q. Do you disagree with the second half of that sentence that reads "States are required to set rates in accordance with regulations at 42 C.F.R. 447.301 to 333"?
A. Again, I probably would choose somewhat different words. The citing of the regulation is correct. But again, there are other things that would -- there are other things that apply. It's a very broad, simplistic statement.
Q. What are the other things that apply?
A. I just -- the economy and efficiency, the integrity of the Medicaid program, requirements to pay correctly. I think there are a number of other provisions that apply to the program as a whole that apply to prescription drugs as well. I don't think the regulations can be -- if you were looking at our entire authority you have to look at the entire statute.
Q. And one of those additional considerations would be to ensure that the

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payment levels are sufficient to ensure access to care for beneficiaries, correct?
MS. MARTINEZ: Objection, form.
A. As we discussed earlier, that is a consideration among a number of considerations.
Q. Are there any others that you can enumerate specifically right here among the other things that you said have to be considered beyond the regulation that's cited in this memorandum?
MR. KELLEY: Objection to form.
A. Well, I think offhand the -- again, broader provisions that apply in terms of state responsibility to maintain the integrity of the program. I think that there are -- as I said, I think it's a broad and overly simplistic statement that doesn't reflect the entirety of the statute.
Q. Are there any other parts or statements in Abbott Exhibit 328 with which you disagree, Mr. Smith?
A. Well, I think, again, there are a number of things in here that perhaps you would

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write more precisely. They use examples rather than being, again, the entirety. For example, in the second paragraph "For dispensing fees we have told the regional offices that they could" -- which implies some discretion in there -- "among other things." So obviously there are other things that could be considered as well.
So, again, I don't know if the intention is for me to rewrite this paper. But I think there are things in the paper that could be developed further if that were appropriate.
I think on the second page -- I think that there are -- the second to the last paragraph on the page, "Because requirements to set dispensing fees are less specific, we would continue to allow states greater flexibility here," again, we could have -- if I were writing this today, I would certainly I think go into greater detail about what that would be. Again, it gives an example, but it doesn't restrict it only to this example.
Q. And which paragraph was that again?

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A. The second from the bottom. It says "for instance."
Q. Okay. Any other parts of it with which you disagree?
A. Again, I think it is a general outline of issues that if you were to develop it more specifically there might be other issues that would be raised.
Q. Are there any factually inaccurate statement in Exhibit 328 of which you're aware?
MS. MARTINEZ: Objection to form.
A. The first sentence on the first page of the second paragraph, "There are two components of this payment rate and each is required to be determined separately," I'm not certain I would agree with that. I think that while they are components -- you could have two components that are -- I think the sentence implies too much, that they are completely on their own, which in fact they do work together.
Q. And when you say "they" you're referring to the ingredient cost and the

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dispensing fee components of the pharmacy payment under Medicaid drug benefit programs, correct?
MR. WINGET-HERNANDEZ: Objection to form.
A. Correct. Because, again, when a state plan amendment comes in we don't ask you for just one or the other, we ask you for both.
Q. And in your experience when CMS evaluates a state plan amendment it looks to both aspects of the state plan, both the ingredient cost and the dispensing fee, in determining whether the payment amount is appropriate and lawful, correct?
A. We do this for the -- it's the methodology to apply to all of the drugs that the program is paying for. That is not drug-specific. The state plan does not list the acquisition cost for every one of the 50,000 individual drugs that Medicaid pays for. So you're describing a methodology that all of the -- that applied to all of the drugs in the aggregate of how they work rather than a drug-

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specific.
So again, I don't think it means that we only care about one or the other. We do care about them both. And they both should be done as accurately as possible.
Q. You testified that the ingredient cost component and the dispensing fee worked together. How do they work together?
A. In terms of a state plan amendment, the state tells us both components in their state plan. You generally would say this is what we are paying. We are paying AWP minus plus a dispensing fee. They would generally come together in a plan amendment.
Q. In your experience has a state ever justified an ingredient cost by reference to a dispensing fee that has not been raised over the years?
MS. MARTINEZ: Objection, form.
A. I'm going to ask you to --
Q. Sure. In your experience have you ever seen a state justifying an ingredient cost at a

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particular level higher than it might otherwise be based upon a dispensing fee that has not been raised over the years?
A. I think that would be a better question for my staff who know these in and out.
Q. Is there any other aspect of the first paragraph there that appears to be factually inaccurate to you?
A. Well, the second to the last sentence and the last sentence in that paragraph again, I think, perhaps would be written more precisely. On the one hand it says "simply required to be reasonable" and the next is "to be comprehensive."
Q. Sure. And for the record I'll read those two sentences. They read "Dispensing fees are simply required to be reasonable. The regulations require that the agency's payment methodology for prescription drugs be described comprehensively in the state plan." And could you tell me again --
A. Well, again, I think that to go back

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and start parsing words and sentences, the dispensing fees are simply required to be reasonable. As I have also testified, we have not simply accepted a state sending in a state plan saying, well, we think this is reasonable. We ask that they be backed up with a study. And as I testified, in particular we disapproved a state plan that the documentation did not support the request of the state.

Q. Were the states trying to pay too much or too little for the dispensing fee, as you recall?

A. As I recall, they were trying to pay -- they were increasing the dispensing fee beyond what was supported in the study. So again, that sentence I think is too simple and doesn't describe either the state's obligation to be reasonable -- we would not accept simply a piece of paper that says we think this is reasonable, please allow it. We have clearly said, no, you have to back it up.

And so as I said, that's why I think I

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would not write it that way.

Q. Is there anything else in that first paragraph on page 1 that you would write differently?

A. I think I've given you several examples. I'll leave it at that at this point.

Q. If you think of anything else later let me know.

A. Okay.

Q. To go back a little bit again to whether this Exhibit 328 is a draft of Exhibit 487, could you compare for me the title of Exhibit 328 to the subject line of Exhibit 487 and confirm for me that both are entitled "review of Medicaid drug state plan amendments"?

A. That is the subject of the October 22nd memo.

Q. And if you go to the end of Exhibit 487 after all the redactions on page 3 it lists out several options, correct?

A. I'm sorry. Which one are you referring to?

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Q. Exhibit 487, the redacted final memo. On page 3 it lists out --

A. Options, yes.

Q. And there are options for ingredient costs and options for dispensing fees, correct?

A. That's correct.

Q. And likewise in Exhibit 328 on page 3 there's a list of options for ingredient costs and options for dispensing fees, correct?

A. That is correct.

Q. And although they are not verbatim the same, can you look at the two and tell me that they roughly follow each other?

A. They roughly follow each other.

Q. And then --

A. As I also testified earlier, for the circumstances, as I recalled, of why the memo was generated was for a particular point in time seeking guidance from the administrator for which we also would be looking for other things as well. I don't think the memo restricts us solely to the enumerated provisions.

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Q. And then on the next page of Exhibit 487 there's a section entitled "recommendations"?

A. Yes.

Q. And followed by decision with an approved line and a disapproved signature line. Do you see that?

A. Yes.

Q. Could you compare the two and confirm for me that other than recommendations being plural in Exhibit 328, the language between Exhibits 487 and 328 are identical on the recommendation paragraph?

A. The form is different. As you stipulated, it's singular rather than plural. The decision memo has a signature block for me on the decision memo.

Q. But the text underneath the title "recommendation," that appears to be identical between the two documents. If you could confirm that for me, please.

A. The wording is the same. I think the wording itself is also important to point out

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that says "On SPAs that did not meet the above criteria, we would not automatically disapprove that SPA," which again provides the understanding that these were not the only things that we were looking at in state plan amendment reviews.

Q. Is there any doubt in your mind, Mr. Smith, that Exhibit 328 is an earlier draft of Exhibit 487?

A. I think that there are a number of similarities. To go back and reconstruct the history of it -- but they certainly relate to -- the topics are related to the memo.

Q. And you would agree with me that it would be preferrable from your point of view at least if I were asking about the final memo rather than an earlier draft, correct?

MS. MARTINEZ: Objection, form.

A. I've pointed out a number of areas that I think the draft -- that in Exhibit 328 I think needs a greater context and understanding than -- it is very difficult in the Medicaid program -- as I've testified, I think there are a number of

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different areas that -- to where these issues need to be looked at in their entirety as the memo itself, the signed memo itself, says. These are among things. These are things that we would look at. But there are other considerations as well.

Q. And some of these ambiguities may have been cleared up in the final version of the memo, correct?

MS. MARTINEZ: Objection, form.

A. I don't recall the final version of the October memo.

Q. Sure. If you go back to Exhibit 328 and the second paragraph on the first page begins with "in practice we have told the states" -- do you see that paragraph?

A. On the second page?

Q. First page, second paragraph.

A. "In practice we have told the states," yes.

Q. Is there anything in that paragraph that is factually inaccurate or with which you

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disagree? Let me be a little more specific.

The first sentence is factually correct. That is, that CMS has told states who wish to modify their estimated acquisition cost levels that they must provide a factual basis to support a change in the EAC or the dispensing fee, correct?

A. I would say that's a correct statement.

Q. And the second sentence, would you also agree with that, that one method to support a change in EAC would be to audit an appropriate number of pharmacies to determine current acquisition costs? Right?

A. I think that's a correct statement, that that would be one way of doing it.

Q. And then the memo drops a footnote at that point. And the footnote reads "States usually base the EAC on average wholesale price levels with a significant discount, for example, AWP less 10 percent." Do you see that footnote?

A. Yes.

Q. Is that consistent with your

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understanding of how states usually base their EAC?

A. They usually do base -- there's variation among the states on what that discount is. Other states also, as I testified earlier, may have a MAC, may have a WAC. Again -- this may be one of the ways that states are pricing their reimbursement system.

Q. The next sentence indicates that CMS has told its regional offices that "In reviewing state plan amendments the regional office should compare rates for contiguous states' rates as well as other states in the region."

A. I would say that's accurate of our practice.

Q. Do you understand that to be been the practice before you arrived at CMS as well?

A. I don't know.

Q. It was a practice that was in existence when you arrived at CMS, though, correct?

A. I think that is how -- one of the factors that was being looked at.

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Q. The next sentence states that "CMS has told regional offices that they should consider drug cost studies." Do I read that correctly?
A. It says -- yes, they should also consider drug cost studies.
Q. And the "they" would refer to regional offices? Am I correct about that?
A. Correct. Let me also point out that at this point in time in 2002 organizationally I don't remember the precise time that we made changes, but when I first arrived at -- it was still HCFA at the time. We changed it to CMS later -- there were a number of reimbursement functions that had been decentralized. One of the things that I did was to centralize a number of reimbursement policies -- reimbursement reviews.
We formed an institutional reimbursement team. We formed -- after 2002, by the way. We formed a noninstitutional reimbursement team. We formed the pharmacy team that precisely was formed to look at drugs. So

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prior to -- I guess I got there in July 2001. I can't make all the decisions the first day. But one of the things that I -- on reimbursement has been a particular issue that central office over time became more involved than prior periods.
So again, when you are reading it you read it in the context that much of it had been decentralized. And over time central office took a greater review of state plan amendments on reimbursement across the board.
Q. Why did you centralize the reimbursement reviews after 2002?
A. We started on the institutional reimbursement side. There is a great deal of concern that providers were gaming the Medicaid system, that the regional offices did not have the expertise to be able to identify what we believed were inappropriate funding mechanisms.
We centralized it to put it in the hands of people who that was their sole responsibility to learn the financing rules and background and to review them on a national basis

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so the decision making would be uniform across the states and would not have the regional variation that had occurred in the prior administration.
I was very concerned when I took the job and I became increasingly concerned over time that we didn't have the expertise through that decentralized process.
Q. How were providers gaming the system with respect to drug payments?
A. Well, I think that the -- I'm trying to sort of step -- I was thinking through it sequentially of what we were looking at at the time.
On the drug payment side I think there was a -- that there was concern about the accuracy of reporting. The -- again, when we looked at AWP as a method, for example, those are reported through different compendium. There was a concern about the accuracy. There is a concern about whether or not we -- again, while we were talking on average prices, could those -- a

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concern of whether or not they were really being monitored over time.
The compendiums that states use in the Medicaid program that other payors have used in the system were relying on these surveys and reports. And again, I think that there was -- I would think it's fair to say widespread concern about the accuracy of those, so much so that in the Deficit Reduction Act of 2005 Congress changed the methodology to inject much more transparency into those systems.
In terms of the previous system of AWP, again, those were reported. There was kind of a middleman in terms of the compendium. Congress changed that entirely and said we're going to a much more transparent -- and I think the rationale was a more reliable -- system of reporting of using the average manufacturer price, which is manufacturers reported directly to HCFA/CMS, for purposes of the rebate side of the prescription drug program.
But on -- you had a system where states

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were paying on AWP but didn't have the accuracy of what the manufacturers themselves were reporting. So the -- I think that it's fair to characterize there was widespread concern that there needed to be more transparency in the system.
Q. Prior to passage of the BRA of 2005, however, you unilaterally centralized the reimbursement reviews in part because of those concerns, correct?
MS. MARTINEZ: Objection, form.
A. There were a number of reasons that we formed the pharm team, again, relying on the expertise of a core group of people. We added people to the pharmacy team. I think we added a pharmacist that hadn't previously been on there. So it certainly was to put a unit together that -- reviewing state plan amendments were certainly part of that, but their overall expertise to deal with a variety of issues.
Q. Did this pharm team have responsibility for reviewing state plan amendments under the

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reorganization that you implemented?
A. They reviewed the state plan amendments, yes. But there's still input from regional offices as well.
Q. Does Exhibit 487 describe the criteria that the pharm team -- and pharm is p-h-a-r-m, right?
A. Yes. That kind of pharm. Not the baseball farm.
Q. Does Exhibit 487 describe criteria that the pharm team used in deciding whether to approve or disapprove state plans?
A. I don't recall how it evolved. Again, this still leaves a lot of room for other considerations. So I don't think it spells out all of the things that we would look at.
Q. But these are some of the criteria?
A. These would be some of the criteria.
Q. Getting back to Exhibit 328, where we left off was a sentence in which CMS indicates that --
A. I'm sorry. Where are you?

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Q. It's the center of paragraph 2.
A. Okay.
Q. It's a sentence that reads "We have also said that they should consider drug costs studies." What do you understand the memorandum to be referring to when it refers to drug cost studies?
MS. MARTINEZ: Objection, form.
A. I would read that as, again, in the context that it was meant of reviewing state plan amendments that they changed their methodologies for how they're paying.
Q. And drug cost studies would include studies such as the OIG reports that are referenced in the following paragraph, correct?
MS. MARTINEZ: Objection, form.
A. I think it refers to what the states should be doing.
Q. And it was your understanding that CMS had told regional offices that states should look to OIG drug cost studies in establishing their estimated acquisition cost formula, correct?

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MR. WINGET-HERNANDEZ: Objection, form.
MS. MARTINEZ: Objection, form.
A. Again, this is what CMS is telling the states to do to say you should do a drug study. I think that that would mean the state would do a drug study.
Q. But was it your understanding the states also could look to OIG reports as another source of data for evaluating whether they were appropriately paying for pharmaceutical products under Medicaid?
A. I think that -- I think in general, being a former Medicaid director and being around Medicaid directors, states tend to look at their own way of putting studies together. An Inspector General report often has limitations to translate it to make it specific to your state. I think most states would look beyond just an OIG study. OIG studies deal typically with samples. Generally a state wants to look within itself to know what's going on within its own jurisdiction.
Q. But you would agree with me that CMS

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expected states to at least consider OIG studies to the extent they were applicable to a particular state's determination of EAC, correct?
MS. MARTINEZ: Objection to form.
A. I don't want to read too much into it. I don't want to read too little into it. I think we simply said that is something you might look at.
Q. It certainly didn't discourage states from looking at OIG studies in establishing estimated acquisition cost, correct?
A. It did not discourage states, no.
Q. That would be one source of potential data recognizing that there may be other even better sources of data that a state could look to?
A. Well, I think not just recognizing. I think that is the reality. I think that a state would want to look within its own state and, as I said, there are limitations to what an OIG study is going to tell you in your particular state.
Q. Other than the fact that an OIG study

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may be looking at more than just one state, are there other limitations that you're referring to?
MR. WINGET-HERNANDEZ: Objection, form.
A. I'm not certain what --
Q. Oh. I just want to make sure I understand your statement. I understand you to be saying that there are limitations to OIG studies because an OIG studies often looks at broader than just a single state. Do I have that correct?
A. That's not the only limitation. I think it would be --
Q. What are the other limitations?
A. I think the sample size. I think the -- I'm not certain I can give you all of the resource limitations that the OIG has in how they design their study, how many samples they go get, how they even pick their studies, what they look for in particular. All I meant to say was I think as a state it wants to look beyond just what an OIG report would be referring to.
Q. The next two sentences relate to

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dispensing fees. Do you see that?
A. "For the dispensing fee"? Is that where you're at?
Q. Yes, sir.
A. Okay. We have said states could establish a reasonable fee.
Q. And there are three methodologies that could be used by states to establish a reasonable fee. Do you see that?
A. It says "Audits and surveys of operational costs, compilation of data regarding professional salaries and fees and analysis of compiled data regarding pharmacy overcosts, profits, et cetera."
Q. Is that an accurate description of the factors that CMS expected states to consider in establishing a reasonable dispensing fee?
MS. MARTINEZ: Objection, form.
A. Again, I think it says "could." And I think it does not limit a state to come up with better ways to put together what they believe to be a reasonable dispensing fee.

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Q. Because under the federal state program in Medicaid, the primary responsibility is on the state to come up with the way to manage their own program, correct?
A. In general, the states set reimbursement. As I said, there are lots of checks and balances that go along with that.
Q. The last sentence there indicates that "For dispensing fees CMS has told the regional offices that it can compare a proposed change to a pricing index such as the consumer price index." Do you see that?
A. Yes.
Q. What do you understand that to be saying?
A. I would just read it as it is. If you're going to make a change you should make some other comparison to what. Drug prices in terms of -- I think that there are -- I think it says you ought to look at -- you're giving an increase. Make it some reasonable comparison to determine what that is.

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I think in drugs in particular one of the areas -- this refers to the dispensing fee. I think it makes -- I think what it's telling the states to do when you're looking at that side of the program, where does it fit within everything else. I mean, it is -- there is a medical inflation index that is often referred to. And as a measurement, as an indicator, anyway, of how do you compare to other indicators.

In terms of drug pricing, again, there's been lots of changes over the years as to how prescription drugs as more drugs come on the market, go to generic, the whole idea of generic is to lower the cost of the drug, to reduce the price that the Medicaid program is paying for it. So again, if you are -- you want to have a comparison. And if what's going on in one place is inconsistent with what you are seeing somewhere else, it should raise some alarm bells to you.

Prescription drugs are -- again, I'm by no means the world's expert on the changes in the

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market of prescription drugs to where you've seen pharmacy benefit managers come and go, generics, authorized generics, the market continues to change. In terms of price competition in the Medicaid program you should be looking for the things that make your prices go down.

Q. When you say you should be looking for things --

A. The state, for example, as it is making comparisons to cost of its program, in general, generics are believed to be beneficial on the price competition side to lower spending. If what you're doing isn't lowering your spending you probably ought to look at that again.

Q. And this reference to the CPI in Exhibit 328 refers to dispensing fees, correct?

A. While it specifically says dispensing fees, I think it would reasonably apply to both.

Q. That annual increases --

A. But we also recognize medical inflation as a whole has generally outpaced the consumer price index, which is -- I think it says related

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price indices. Again, we didn't -- if I were -- to my thinking related price indices would, while this specifically says consumer price index, it would be reasonable to also say the medical price index, the component -- medical costs do rise faster than general inflation. They have for a number of years now.

Q. The next paragraph describes some recently issued OIG reports compare average wholesale price to actual acquisition cost. Do I have that correct?

A. Yes. It's referring to recent OIG reports and doesn't give me what reports they are or the time frame.

Q. The final memo was -- that's marked as Exhibit 487 -- was issued in October 2002, correct?

A. Exhibit 487 was October 22nd.

Q. Right. If you could turn to Exhibit 329 in the book to your left -- it's just tab over, I believe. That's a March 14, 2002 Office of Inspector General report entitled "Medicaid

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Pharmacy Actual Acquisition Cost of Generic Prescription Drug Products." If you could take a quick look at that, do you recall that report?

A. Not offhand. I'd have to read it first, if I may.

Q. Certainly. Please. Take your time.

MS. MARTINEZ: Mr. Cook, I think we've gone more than an hour.

MR. COOK: Oh, I apologize. Why don't we take a break. Off the record, please.

THE VIDEOGRAPHER: This is the end of tape 4. Off the record at 3:25.

(Recess.)

THE VIDEOGRAPHER: This is the beginning of tape 5 in the deposition of Mr. Smith. On the record at 3:40.

BY MR. COOK:

Q. Mr. Smith, have you had a chance to examine Exhibit 329?

A. Yes. I have looked at parts of it. I haven't read it in its entirety. But it's starting to bring back some memories.